ARC 0172C

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 124.301 and 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 11, "Drugs in Emergency Medical Services Programs," Iowa Administrative Code.

The amendments were approved at the April 27, 2012, regular meeting of the Board of Pharmacy.

The proposed amendments exclude nonmedicated intravenous solutions from the definition of "drug" as that term is used within the chapter and specify that records that are required to be maintained by or within an emergency medical services (EMS) program under this chapter are to be maintained and made available for inspection and copying by the Board, the Board's representative, or another authorized individual. The proposed amendments provide that the monthly inspection of drug supplies maintained at the primary emergency medical services program site may be inspected by a pharmacist, a pharmacist-intern, a certified pharmacy technician, or the service director if the program is a pharmacy-based service or by the medical director, service director, or other designated EMS personnel if the program is a medical director-based program. The proposed amendments also clarify the content and format of the required record to be kept following the administration of a controlled substance.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on July 6, 2012. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code chapter 147A and sections 124.301 and 155A.13.

The following amendments are proposed.

ITEM 1. Amend rule **657—11.1(124,147A,155A)**, definition of "Drug," as follows:

"Drug" means a substance as defined in Iowa Code section 155A.3(13) but does not include nonmedicated intravenous solutions such as saline.

ITEM 2. Amend subrule 11.4(2) as follows:

11.4(2) *Medical director-based programs.* Immediately upon discontinuation of services, all controlled substances shall be jointly inventoried by the medical director and the service director or their respective designees. A record of this inventory shall be maintained by the medical director for two years and be available for inspection and copying by the board, ~~or its~~ the board's representative, or another authorized individual. All drugs and devices that are the property of the medical director shall be immediately returned to the medical director.

ITEM 3. Amend subrule 11.11(1) as follows:

11.11(1) Each service program shall, jointly with the service director and the responsible individual, develop, implement, and adhere to written policies and procedures for the operation and management of the service program with respect to prescription drugs and devices. These policies and procedures shall be available for inspection and copying by the board, ~~or its~~ the board's representative, or another authorized individual. The policies and procedures shall be periodically reviewed by the responsible

individual, the medical director, and the service director. Documentation of the review shall be maintained.

ITEM 4. Amend subrule 11.20(1) as follows:

11.20(1) *Pharmacy-based.* The pharmacist in charge, the medical director, and the service director shall jointly develop a list of drugs to be maintained for administration by the service program. The pharmacy shall maintain an accurate list of all prescription drugs including controlled substances that the pharmacy maintains at the primary program site and at any program substation.

a. Replenishment. The responsible individual, the service director, or designee may request that replenishment supplies of drugs be maintained at the primary program site provided that the pharmacy has been supplied with administration records justifying the order. Records of the administration of Schedule III, IV, and V controlled substances and noncontrolled prescription drugs provided to and maintained at the pharmacy shall include, at a minimum: the patient's name; the name, strength, dosage form, and quantity of the drug administered; and the date administered. Records of the administration of Schedule II controlled substances provided to and maintained at the pharmacy shall consist of a written prescription including all of the prescription information required pursuant to Iowa Code section 155A.27 or a copy of the patient care record if the patient care record includes the required prescription information. The pharmacist shall approve every drug taken from the pharmacy's dispensing stock prior to the transfer of the drug to the primary program site. Documentation of this verification shall be maintained within the pharmacy records.

b. Inspections. The pharmacist in charge shall ensure the completion of a monthly inspection of all prescription drugs maintained by the pharmacy at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. All drugs removed from administration stock shall be returned to the pharmacy. Records of inspection shall be maintained for two years at the pharmacy. The pharmacist in charge may delegate the conduct of the monthly inspection to another pharmacist, a pharmacist-intern, a certified pharmacy technician, or the service director.

ITEM 5. Amend paragraph **11.20(2)"b"** as follows:

b. Inspections. The medical director shall ensure the completion of a monthly inspection of all prescription drugs maintained by the medical director at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. Records of inspection shall be maintained for two years at the primary program site or the program substation. The medical director or service director may designate EMS personnel to conduct required inspections.